REVIEW OF BIOTECHNOLOGY IN AGRICULTURE

HEARING

BEFORE THE

SUBCOMMITTEE ON CONSERVATION, CREDIT, RURAL DEVELOPMENT, AND RESEARCH

OF THE

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REVIEW OF BIOTECHNOLOGY IN AGRICULTURE

TUESDAY, JUNE 17, 2003

HOUSE OF REPRESENTATIVES,
SUBCOMMITTEE ON CONSERVATION, CREDIT,
RURAL DEVELOPMENT, AND RESEARCH,
COMMITTEE ON AGRICULTURE,
Washington, DC.

The subcommittee met, pursuant to call, at 11:00 a.m., in Room 1302 of the Longworth House Office Building, Hon. Frank D. Lucas (chairman of the subcommittee) presiding.

Present: Representatives Osborne, Putnam, Burns, Bonner, Rogers, King, Goodlatte [ex officio], Holden, Case, Ballance, Peterson, Etheridge, Acevedo-Vilá, and Marshall.

Staff present: Ryan Weston, subcommittee staff director; John Goldberg, Anne Hazlett, Elizabeth Parker, Dave Ebersole, Callista Gingrich, clerk; Elyse Bauer, Jon Hixson, Claire Folbre, Kellie Rogers, and Russell Middleton.

OPENING STATEMENT OF HON. FRANK D. LUCAS, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF OKLAHOMA

Mr. LUCAS. The hearing of the Subcommittee on Conservation, Credit, Rural Development, and Research to review biotechnology in agriculture will come to order. And I would like to welcome to the subcommittee's hearing regarding biotechnology today.

I can think of few technologies that provide as much hope for the future as biotechnology. The fact that we are able to create healthier, environmentally friendlier, and higher yielding crops as a result of modern biotechnology should not be taken lightly. The process of creating desired traits through conventional breeding has been used for centuries. The problem has been the time needed for the trial and error necessary for conventional breeding that can take decades, and sound results can sometimes be very elusive.

Conventional breeding is a science and, yes, an art form. Not only do you get some of the desired traits from crossbreeding, but you also get many traits that may not be so desirable. The fact that modern biotechnology focuses on using the exact genes needed to express a particular trait has allowed us to leap, literally, light years forward and vastly expand our realm of possibilities.

I was quite surprised by some of the comments made last week during debate on House Resolution 252. The United States' decision to go before the World Trade Organization in an attempt to end the European Union's 5-year moratorium on the approval of

new agricultural biotechnology products, which does not take away any of the European sovereignty. Waiting for 5 years to see if the EU would take any steps to explain their action, or should I say inaction, has been more than fair.

It should also be made clear that farmers are embracing products of biotechnology. Cotton, corn, and soybean farmers, in particular, have found that biotech crops have allowed them to cut down on input costs while maintaining, or even increasing, yields. Small subsistence farmers in third world countries may have the most to gain from biotechnology. Once crops that can survive local conditions or specific yield nutrition benefits are available, these farmers will be better able to support themselves and help protect their communities from famine.

Finally, some statements on the House floor erroneously suggested that products of biotechnology are not regulated. I find this quite interesting that I have before me three witness from three different agencies, all of them having a hand in regulating products of biotechnology.

We live in a world where new developments in science have revolutionized how we live and how long we live. We can cower in fear of science every morning when we wake up, or we can get out of bed, turn on the electric lights, eat our breakfast foods that are able to be stored longer and kept fresher than ever, and then get into our car and drive to work as we all sit down in front of our computer terminals. My point is that science is all around us. It isn't going away, and congress will continue to regulate science and its innovations as it sees fit.

Biotechnology and its regulatory structure have been developed during both Republican and Democratic administrations and Republican and Democratic Congresses. Debate over the appropriate amount of regulation has occurred in the past and will likely continue into the future. Everyone has had their chance to impose changes in the regulatory structure. Most importantly, we must base our legislative decisions on sound science and not, I repeat, not unfounded assumptions.

Today's hearing is a great opportunity for our subcommittee. We have asked our witnesses to explain their federal responsibilities for regulating genetically modified foods and plants.

In 1984, the White House Office of Science and Technology Policy published its "Coordinated Framework for Regulation of Biotechnology". This framework proposed that products of biotechnology would be regulated according to their characteristics and novel features and not by their method of production. It further proposed that new biotechnology products be regulated under the existing web of federal statutory authority and regulation.

In 1986, that same OSTP finalized the coordinated framework. This allowed each agency to know who should be the lead agency and to encourage coordination whenever jurisdiction overlapped. The U.S. Department of Agriculture regulates importation, interstate movement, and environmental release of transgenic plants that contain pest components. The Food and Drug Administration is responsible for regulating food and feeds in the market that have been modified through biotechnology. And the Environmental Protection Agency registers certain pesticides produced in plants prior

to their distribution and sale. And it also establishes pesticide tolerances in foods.

It is very tricky to navigate the details of where one agency's jurisdiction ends and another begins; yet I believe this is very important for the subcommittee members to know the details. It is my understanding that the administration is currently reviewing the Coordinated Framework. If, in the future, any changes are proposed, it is imperative that we know why those changes should be considered.

There are many topics that we will discuss today, and I hope to keep the focus on the Coordinated Framework and time allowing any current or future proposed rules and regulations concerning plant-made pharmaceuticals, PMPs, plant-made industrial products, PMIPs, and plant-incorporated protectants, PIPs, to be discussed. Yes, that is a lot of acronyms.

I would note that the witnesses have also mentioned, in their testimonies, instances when they have had to take action to ensure the public and the environment safety. They should be commended for taking appropriate actions, but we should strive to do all that is possible to prevent these types of concerns from arising in the future.

The testimony before us today does get into the details, and I look forward to hearing from the witnesses. And with that, I turn to the ranking member, Mr. Holden, for any opening statements he may have.

OPENING STATEMENT OF HON. TIM HOLDEN, A REPRESENTATIVE IN CONGRESS FROM THE COMMONWEALTH OF PENNSYLVANIA

Mr. HOLDEN. Thank you, Mr. Chairman, for holding this hearing to review biotechnology in agriculture. Hopefully, this hearing will provide us all an opportunity to understand how USDA, FDA, and EPA work together to ensure a safe food supply in a growing industry.

At some point in time, we have all consumed genetically modified food. A majority of products in supermarkets have been altered in some way. The biotechnology industry has seen rapid growth over the past decade. Employment has doubled, revenues have tripled, and research and development investment has quadrupled. The industry has seen many breakthroughs in revolutionized food processing, but not without debate. Farmers have contributed greatly to the success of the industry. They have been crossbreeding varieties for centuries and have been adopting biotechnology in an effort to improve yield while increasing efficiency and competitiveness.

The agriculture industry has recognized the potential benefits, and now we must help educate the public that we can produce safe food if technology is allowed to advance. While the proper balance of testing must be achieved, we must allow for innovation. We are in a common debate with opponents calling for tighter controls and supporters believing the necessary structure is in place.

Mr. Chairman, I look forward to the testimony that we are going to hear today as we learn more about the biotechnology regulatory framework.

Thank you, Mr. Chairman.

Mr. LUCAS. The Chair thanks the ranking member for those opening comments, and would note that he requests that any other Members submit their opening statements for the record so that the witnesses may begin their testimony to ensure that we have ample time for questions.

And with that, I would like to invite the rest of the first panel to come to the table and join Mr. David Hegwood, Special Counsel to the Secretary of Agriculture, U.S. Department of Agriculture. We also have Dr. Lester M. Crawford, Deputy Commissioner for Food and Drugs, U.S. Food and Drug Administration, and Mr. Stephen L. Johnson, Assistant Administrator, Office of Prevention, Pesticides, and Toxic Substances, U.S. Environmental Protection Agency.

And with that, Mr. Hegwood.

STATEMENT OF DAVID HEGWOOD, SPECIAL COUNSEL TO THE SECRETARY, U.S. DEPARTMENT OF AGRICULTURE

Mr. HEGWOOD. Thank you, Mr. Chairman, and members of the committee, for the opportunity to be here with you this morning. I will make a brief oral statement and ask the committee to accept my written statement for the record.

Biotechnology is probably the most important technological development ever introduced in agriculture. It is the driver of profound changes in the global food and agriculture system. As an early adopter and aggressive user of the technology, U.S. agriculture is experiencing the tremendous benefits as well as the complex challenges of biotechnology.

USDA has a broader role in biotechnology than any other agency in government. Biotechnology impacts nearly every program area within the Department, from the Agricultural Research Service to the Foreign Agricultural Service. Our responsibility at USDA is to foster the development of biotechnology as a tool that can improve the food and agriculture system while, at the same time, ensuring that it is used in a manner that ensures the health and safety of U.S. agriculture, the American public, and the environment.

Today I want to focus on the Department's regulatory role in biotechnology. Working together under the Coordinated Framework since 1986, USDA, the FDA, and the Environmental Protection Agency have created a robust, effective, and efficient regulatory system for products derived from modern biotechnology. USDA's Animal and Plant Health Inspection Service, under the authorities in the Plant Protection Act, regulates the interstate movement, importation, field testing, and release of bioengineered plants, insects, and microorganisms through permitting and notification procedures. In general, APHIS's field testing requirements for regulated plants are designed to prevent the unintentional environmental introduction, whether by pollen movement, seed or grain commingling, or other means of any protein or trait produced in these plants that would present a risk or potential risk to agricultural crops or the environment.

APHIS operates a permit system for the field testing of genetically engineered crops. Companies that wish to field test such crops must submit detailed applications to the agency with information

about the plant variety being tested, the purpose of the test, how it will be conducted, and the specific confinement conditions taken to prevent the escape of pollen, plants, or plant parts from the field test site.

APHIS also has a streamlined permitting process called notification in place for certain types of low-risk plants. Most of the field tests carried out in the United States are done under notification. Compliance and enforcement are critical components of the regulatory system. All field test sites are subject to APHIS inspection. Field test sites under permit are inspected at least once during the current growing season. APHIS has a range of enforcement authorities up to and including civil and criminal penalties.

After successful completing the field testing stage of a new plant variety's development, a permit holder can petition APHIS to deregulate the biotechnology crop. In considering the petition, APHIS carefully reviews the data submitted by the permit holder and also weighs other pertinent scientific studies and information. APHIS bases its deregulation decision on a determination that the plant poses no pest risks to other crops or plants.

Once APHIS deregulates a particular product, the company must still comply with applicable FDA or EPA requirements prior to marketing. These requirements, coupled with APHIS's inspections and oversights, provide a scientifically sound regulatory scheme for the safe field testing of bioengineered plants in the United States.

In an effort to stay ahead of potentially regulatory challenges, the administration is also looking closely and proactively at the rapidly developing science and how the science is being applied to potentially new products. Some examples of our efforts include in August 2002, the White House Office of Science and Technology Policy published a notice in the Federal Register relating to the inadvertent and low-level presence of varieties being developed for food or feed purposes that have not completed applicable agency review. In this Federal Register notice, APHIS proposed to update requirements for field testing of genetically engineered plants. USDA, EPA, and FDA have received comments regarding this notice and are in the process of developing those appropriate responses. The White House's Agricultural Biotechnology Working Group is looking at regulatory challenges posed by plants genetically engineered to produce pharmaceuticals and industrial chemicals. I want to emphasize that APHIS already subjects these crops to more restrictive confinement conditions than most genetically engineered crops.

And finally, in June 2002, APHIS established a new biotech unit to consolidate and better coordinate its services and activities in this area. The new unit, Biotech Regulatory Services, is responsible for programs focusing on both plant-based and animal-based biotechnology. We plan to strengthen the BRS inspection and compliance unit, which conducted 305 inspections in 2002, and we estimate that that will double this growing season. Taking together these steps in conjunction with the continued collaboration with the EPA and FDA officials ensure that USDA is fully prepared to meet the present and future regulatory challenges arising from biotechnology while allowing U.S. agriculture and the rest of the world to realize the potential of this important technology.

Thank you again for the opportunity to be here today, and I look forward to answering your questions.

Mr. LUCAS. Thank you, Mr. Hegwood.

Dr. Crawford.

STATEMENT OF LESTER M. CRAWFORD, DEPUTY COMMISSIONER FOR FOOD AND DRUGS, U.S. FOOD AND DRUG ADMINISTRATION

Dr. CRAWFORD. Thank you very much, Mr. Chairman.

I am Les Crawford, Deputy Commissioner of Food and Drugs. Thank you for the opportunity to testify here today about how FDA regulates genetically engineered foods, or bioengineered foods, as we prefer to call them. FDA also regulates bioengineered drugs, medical devices, biologicals, and veterinary products.

We are confident that the bioengineered plant foods on the market today are as safe as their conventional counterparts. Both the General Accounting Office and the National Academy of Sciences have issued reports agreeing with this assessment. FDA has reviewed the data on more than 50 bioengineered food products ranging from herbicide-resistant soybeans to modified canola oil, and there is a list of these products on our website.

After 10 years of experience in this country, there is every reason to conclude that bioengineered foods are as safe as food produced through traditional breeding techniques. In a 1992 policy statement on bioengineered foods, FDA announced that the agency was "not aware of any information showing that foods derived by these new methods differ from other foods in any meaningful or material way or that, as a class, foods developed by the new techniques present any different or greater safety concern than foods developed by traditional plant breeding." This statement was based on two separate reports issued by the National Academy of Sciences. The 1992 statement and its scientific underpinnings still reflect the FDA's thinking about bioengineered foods.

Please allow me to add some perspective to the aforementioned statements. Scientists have been improving plants by changing their genetic makeup for years through crossbreeding and hybridization in which two related plants are cross-fertilized and the resulting offspring have characteristics of both parent plants. In the breeding process, however, many undesirable traits often can appear in addition to the desirable ones. Some of those undesirable traits can be eliminated through additional breeding, which is time consuming. Breeders can then further select and reproduce the offspring that have the desired traits. Many of the foods that are already common in our diet are obtained from plant varieties that were developed using conventional genetic techniques of breeding and selection. Hybrid corn, nectarines, which are genetically altered peaches, and tangelos, which are a genetic hybrid of a tangerine and grapefruit, are all examples of such breeding and selection.

Today, by inserting one or more genes into a plant, scientists are able to produce a plant with new, advantageous characteristics but with greater precision. The new techniques give scientists the ability to isolate genes and introduce new traits into foods without simultaneously introducing undesirable traits. This is an important

improvement over traditional breedings. Are there risks? Any genetic modification technique, including both traditional methods and bioengineering, could change the composition of a food in a manner relevant to food safety. But because of the increased precision offered by bioengineering, it is our conclusion that the risk of introducing detrimental traits is actually likely to be lessened.

Bioengineered foods and food ingredients must adhere to the same standards of safety under the Federal Food, Drug and Cosmetic Act that applied to their conventionally bred counterparts. This means that these products must be as safe as the tradition foods in the market. FDA has broad authority to initiate regulatory action if a product fails to meet the requirements of the Food and Drug Act.

FDA has established a consultative process to help companies comply with the FD&C Act's requirements for bioengineered foods that they intend to market. Companies have used the consultative process more than 50 times as they sought to introduce genetically altered plants representing 12 different crops into the U.S. market. We are not aware of any bioengineered plant food that is subject to FDA's jurisdiction and is on the market that has not been evaluated by FDA and through the current consultation process.

On January 18, 2001, FDA published a proposed rule to require that developments of bioengineered plant varieties notify FDA of their intention to market such products. FDA proposed that specific information be submitted to help determine whether the foods pose potential safety, labeling, or adulteration issues. The comment period for the proposed rule has closed, and the agency is in the process of evaluating the many comments received. The proposal has raised policy and legal concerns and is not a public health rationale for FDA given there is a voluntary consultation process in place that is working well.

With respect to pharmaceutical crops, the FDA has the authority and responsibility for regulating pharmaceuticals whether they are manufactured in a traditional manufacturing plant or they are manufactured in crops in the field. For crops in the field, however, there are additional issues to be addressed related to the parts of the plant that do not contain the pharmaceutical and the residual crop left over after the pharmaceutical is extracted. We at FDA are evaluating ways to help keep pharmaceutical and industrial chemical material out of food when it isn't supposed to be there that would be science-based and risk-based that would be enforceable and that would not pose too high a barrier to development of these crops.

Mr. Chairman, we thank you very much, indeed.

[The prepared statement of Dr. Crawford appears at the conclusion of the hearing.]

Mr. LUCAS. Thank you, Dr. Crawford.

Mr. Johnson.

STATEMENT OF STEPHEN L. JOHNSON, ASSISTANT ADMINISTRATOR, OFFICE OF PREVENTION, PESTICIDES, AND TOXIC SUBSTANCES, U.S. ENVIRONMENTAL PROTECTION AGENCY

Mr. JOHNSON. Good morning, Mr. Chairman and other members of the committee. I certainly appreciate the opportunity to be here

today. I would like to make a brief oral testimony and then I would like to ask that my written statement be entered into the record.

Mr. LUCAS. So ordered.

Mr. JOHNSON. Thank you.

I am pleased to be here with my colleagues from FDA and USDA to talk about how we regulate biotechnology in the Federal Government. The three agencies here today have a lot of experience and insight into the regulation of biotechnology. And the administration looks forward to working with this committee on biotechnology.

I want to stress up front that biotechnology holds tremendous promise. It can bring better solutions to our society. And at EPA, we believe it can provide opportunities that benefit the protection of human health and our environment. This is important technology. As you know, the regulation of biotechnology is spread between the three agencies. We believe that the existing regulatory system is working well and produces decisions that are scientifically sound and defensible. Our goal is to ensure that our regulatory decisions are based on rigorous scientific information, the highest scientific standards with a high degree of transparency.

Under the Coordinated Framework, EPA regulates pesticide products under the Federal Insecticide, Fungicide, and Rodenticide Act, also known as FIFRA, and section 408 of the Federal Food, Drug, and Cosmetic Act, or FFDCA. EPA also regulates biotechnology under the Toxic Substances Control Act, or TSCA. Biotech pesticide products regulated under FIFRA and FFDCA include bioengineered microorganisms with pesticidal action as well as products produced by plants that act within the living plant as pesticides to protect the plant.

This latter category are called "plant-incorporated protectants" or "PIPs." The leading example of these plant-incorporated protectants or plants which contain genes from Bacillus thuringiensis or simply Bt. The plant can now synthesize its own Bt protein and ward off pests.

EPA has a long history in biotechnology in developing a comprehensive regulatory program for pesticide products. In fact, the agency has been working with companies and individuals to regulate biotech products since the 1980s. Throughout these years, the agency has developed robust regulatory and scientific standards for biotechnology products going through the registration or licensing process.

Let me briefly discuss the requirements of our registration process. First, a potential registrant typically comes in for a meeting with our scientific staff at which time we decide upon the appropriate or product-specific data requirements. The registrant generates a wide range of data, submits it to EPA for our review. We require scientific data in at least five categories: product characterization; toxicology, including allergenicity; non-target organism effects, particularly focused on birds, fish, and beneficial organisms; exposure and environmental fate, including gene transfer; and resistant management. These data that are developed are then carefully reviewed by agency scientists. If any concerns or questions arise in any one of the categories of tests described, a higher tier of testing is required to allow EPA to more thoroughly evaluate the potential risks.

Also, given the scientific nature of our regulatory decisions, EPA routinely consults with our scientific advisory panel, an outside panel of experts, as well as the USDA and FDA and others to ensure that the science supporting our regulatory decisions is sound. The agency carefully evaluates the available data and the product labeling to determine if the available information meets the established scientific and regulatory standards. Our standard is to ensure that the product can be used safely and will not cause any harm to people or the environment. Our average time to review and reach a decision on a new plant-incorporated protectant is between 24 and 30 months. Currently, EPA has registered 11 separate products, biotech products, the crops that have included potatoes, cotton, field corn, sweet corn, and popcorn.

EPA also administers regulatory oversight over commercial introduction of new microorganisms and significant new uses of existing microorganisms under the authority of the Toxic Substances Control Act. This law gives EPA the authority to take any action on "chemical substances" that may present an unreasonable risk of injury to health or the environment.

In conclusion, I would like to thank you for allowing EPA to share our experience with biotechnology. The agency's biotechnology program is based on five important principles: sound science, transparency in decision making, consistency and fairness, collaboration with our regulatory partners, and building public trust, all of which help to ensure environmental and human health protection is achieved. Given our intellectual and scientific investment in regulating biotechnology, the agency stands ready, working with our partners at USDA and FDA, to meet the future challenges necessary to safeguard this technology for the future.

I would now be happy to answer any questions that you may have. Thank you.

[The prepared statment of Mr. Johnson appears at the conclusion of teh hearing.]

Mr. LUCAS. Thank you, Mr. Johnson.

Clearly, the administration places a significant importance on agriculture and food biotechnology by the recent actions in filing the case against the moratorium on new biotech crops by our friends in the European Union. I guess what I would like for you to do for a moment is, perhaps starting with you, Mr. Hegwood, whether it is to pick out some product that successfully made its way through the process like soybeans or any product, explain for the committee what the process would be and how the three entities work together in a concise fashion. I have a biotech company, and I want to develop a new product, and I assume I come see you first.

Mr. HEGWOOD. Yes, sir, Mr. Chairman. The USDA has what could be termed the "gatekeeper" role. We are the first stop for any company that would want to come in and conduct a field trial. We would have a consultation with the company, talk about the data requirements. If they wanted to do field testing, we would come to an agreement on the specific requirements, confinement requirements for the field testing, look at the purpose for the field test, the purpose for the product, and look at the genetic sequencing. And then, depending on the type of product, we would also have discussions with EPA and FDA about requirements that we would

have to make our requirements consistent with what EPA and FDA would require to meet their objectives.

Mr. LUCAS. So in that first stage, I would come to you. I would have to have a plan of action. I would have to justify what I was endeavoring to do, discuss the genetics. I would have to have a plan for how to control the endeavor. And at that point, if I pass muster, I would proceed to the next step, and depending on the product, then I would turn to your friends here, and they would——

Dr. CRAWFORD. If it is a food, a bioengineered product intended to be a food, they would come to FDA after the APHIS pass-off, and we would have a consultation with them in terms of what we needed with respect to data. They would share with us their research plan. We would critique it and then there would be a follow-up consultation once they had completed these studies. And we would evaluate that and then advise the company of the suitability of product for inclusion into the U.S. food supply. There may be more consultations in between the first one and the second one, depending on the kind of product.

Mr. LUCAS. But just because I came first to USDA and then potentially to Food and Drug with a concept, an idea, doesn't necessarily mean that either entity would grant approval? But if I convinced both entities, then potentially, our friends at EPA would be a factor?

Mr. JOHNSON. Well, again, in the EPA's case, if the initial consultation with the Department of Agriculture was that it was going to be pesticidal, for example the Bt was going to be inserted into a particular plant, and they wanted to claim the pesticidal property, then after the initial consultation with the Department of Agriculture, then they would come to EPA. And then we would have a consultation and then sit down and describe the specific data requirements. And we are looking at both the potential environmental effects as well as the potential human health effects.

It is EPA's responsibility for pesticides to not only look at the environment but also to determine whether, in fact, this particular pesticidal gene would be safe in food. And that authority comes from the Federal Food, Drug, and Cosmetic Act, similar to the way a chemical pesticide is. Again, we evaluate a chemical pesticide for both its effects on the environment as well as potential human health in the food. And then we would either establish a tolerance, that is the maximum allowable of the particular material, or an exemption from tolerance saying that it was safe and it was not necessary to set a level.

Mr. LUCAS. Fascinating. Having to clear all three entities depending on the nature of the product. One last question on this first round: are you confident, each of you, in the way your agencies work together? Are you confident that every opportunity is being utilized to work among agencies and among the rest of the Federal Government? Do you believe that the Framework now provides a sufficiently restrictive and very methodical process? Any or all.

Mr. JOHNSON. Mr. Chairman, I think, first, we, at EPA, believe that the Coordinated Framework has, and continues to, serve us very well and that the working relationship across the three agen-

cies is very, very strong. And but as you are probably well aware, we are continuing to look at the Coordinated Framework. And if there are needed improvements, then we will make those recommendations. But certainly, for EPA's perspective, it has and continues to serve us very well.

Dr. CRAWFORD. FDA is also confident in the Coordinated Framework, and we believe that relations between EPA and USDA in this regard are very, very good, indeed. And the system, in fact, is working.

Mr. HEGWOOD. I would just reinforce my colleagues. We have absolute confidence in the system as it exists. And the Coordinated Framework has been tested time and again, and we believe it provides adequate, effective regulatory framework for these products. And of course, we always need to make sure that we are keeping up with the technology, and we are doing that.

Mr. LUCAS. Thank you, gentlemen, for your insights.

I turn to the ranking member, Mr. Holden, for any questions he might have.

Mr. HOLDEN. All right. Thank you, Mr. Chairman, and I thank the panelists for their testimony.

My question on coordination has been answered, but my next question has to do with the resources. And I would ask each of our panelists: do you believe that your agency has the adequate resources and funding to approve new bioengineered agriculture products in a timely manner and perform the best possible oversight of these products?

Mr. HEGWOOD. We believe we have adequate resources to do what we need to do now. One of the things that we are doing is looking ahead, trying to gauge where the technology is going and what impact that is going to have on USDA's resource requirements. We have recently established an advisory committee on biotechnology for the Secretary, and this is specifically one of the issues that they will be looking at. So we do anticipate that in the future we will have to address the issue of resources, but we believe we are able to do what we need to do with the resources we have got now.

Mr. HOLDEN. Dr. Crawford.

Dr. CRAWFORD. FDA, likewise, believes we have adequate resources. I agree with Mr. Hegwood that we have to stay ahead of the research that is being developed, the new products that are coming. So it requires an exquisitely productive relationship with USDA's regulatory apparatus as well as its research apparatus, but also such entities in the government as EPA and the National Institutes of Health. And it is necessary for us to work very carefully with them and also with the industry to know what is coming. Our first responsibility is public health, but we also don't want to array ourselves in such a way that we impede either the research or the development of the industry. And at the present time, we think we are able to keep up, and we also believe that we do know what is being developed and what is coming, and I think we can do an adequate job of dealing with it from a regulatory and public health perspective.

Mr. HOLDEN. Mr. Johnson.

Mr. JOHNSON. Thank you, Mr. Holden.

We, too, believe that we have adequate resources to review the license applications that we receive. We are also very much aware of both the importance of the technology as well as what we see on the horizon. And again, we believe we have adequate resources, of course, as the technology continues to grow and expand, then we will have to revisit the resource issue.

Mr. HOLDEN. Thank you.

One last question, Mr. Chairman, for Dr. Crawford. We know that other countries are developing and growing products derived from biotechnology.

Dr. CRAWFORD. Yes.

Mr. HOLDEN. What authority exists for the FDA to monitor, enforce, and require safety assessments for potential biotech imports?

Dr. CRAWFORD. The products that are coming into the country from other countries also require the same kind of evaluation. If these products are coming from countries that we have regular trading agreements with, we have to be assured that the product is either approved in this country and is being brought in from another country or if it is bioengineered, we need to have an analysis. So we would follow the same exact concerns and same exact process for imported products as we would for domestically produced products.

Mr. HOLDEN. Thank you, Dr. Crawford. And thank you to our panelists, and I would yield back, Mr. Chairman.

Mr. LUCAS. Thank you, Mr. Holden.

The gentleman from Alabama, Mr. Bonner.

Mr. BONNER. Thank you, Mr. Chairman.

Dr. Crawford, listening to your testimony about food safety and realizing that this stretches a little bit away from the subject of biotechnology. I would like to take advantage at this opportunity to ask you a question. I come from the Gulf Coast, south Alabama, where we have had a number of shrimpers in my District that have been adversely affected by the importation of shrimp that contained chloramphenicol. It has not only devastated the shrimpers, but it has had a rippling effect throughout the economy with regard to the people who supply the shrimp boats, build the shrimp boats, the banks that loan the money, and other things as well. And I was wondering, can you tell me what, if anything, FDA has done to determine whether the introduction of chloramphenicol into the American diet has had any negative impact with regard to the importation of the shrimp that are coming into our country.

Dr. CRAWFORD. Well, thank you. I used to feast on those shrimp and oysters from the vantagepoint of Demopolis, Alabama, a little further north. And that is why I grew up to be a strong, healthy American, also. Chloramphenicol does not belong in the food supply at all. As you know, USDA and FDA have worked very hard to keep it out. FDA has had some notable episodes in its history, particularly in the early 1980s, the illegal use of chloramphenicol by livestock producers and have clamped down, eliminated. We have done the same thing with importations of seafood products and also honey. We have developed new, more sensitive tests to deal with it. We have also met with the Chinese Government and others that can help us with this process, since most of those products, as you know, came from that part of the world. And we believe we have

made great progress. We think we just about have eliminated any threat to the American food supply. However, we will continue to monitor the food supply in all aspects, not just shrimp, not just honey, but also various other things that we think would be subject. And we will be testing as well as monitoring, and that is going to give us the satisfaction that this does not enter our food supply, because chloramphenicol has no business being in any food that is consumed at any level.

Mr. BONNER. Thank you, Mr. Chairman.

Mr. LUCAS. Thank you. The Chair turns to the gentleman from Georgia, Mr. Marshall.

Mr. MARSHALL. Thank you, Mr. Chairman.

I must admit that I suffer from a great deal of ignorance about this subject matter, and I don't worry about what I eat. I just trust you guys to make sure that what I eat is appropriate. Mr. Chairman, I don't know how the panel was chosen today. I am a lawyer who is used to sitting in on arguments where people disagree with one another, and it seems like the three of you pretty much agree with one another. And Mr. Chairman, I suppose it would be helpful to me to have a debate on these subjects, if that can be arranged at some point in the future.And I guess my question to any of the panelists would be who are the naysayers here, besides the French? They don't count in my book right now. But who are the nay-sayers, the folks with some credibility who think that either biotechnology generally is very threatening to us or that the process we go through in regulating biotechnology is inadequate?

Dr. CRAWFORD. Yes. Thank you for the question. I think in the scientific and medical community worldwide, there is little disagreement. I think when bioengineering first came on the market, if you will, in the 1980s, as we evaluated what the prospects were and what the safety factors were, we asked the National Academy of Sciences here in the U.S. to do a couple of reports. And they concluded two things that have turned out to be true now that we have had 10 years of consuming these products. The first was that there is no inherent reason that bioengineered foods would be unsafe. And then the second thing is that because the technology is so sensitive and precise, there is every reason to expect that they might even be safer. And so I think that remains to be what the consensus of opinion is in the scientific community.

There are some trade issues with biotech foods, but I don't think they are science based.

Mr. JOHNSON. Yes, Mr. Marshall. Among the comments that we have heard of some of the issues related to biotech, in addition to what Dr. Crawford has mentioned, deal with the environmental issues. One of them being gene drift, can the genes from a bioengineered plant drift to a non-engineered plant or to a weed, for example? Issues of resistance, could insects become resistant to the particular bioengineered material faster or in a worse way than insects to a conventional chemical?

And then there have been some issues that have come up related to specific issues, animals or insects, such as the Monarch butterfly. In each of those instances, for example, the Monarch butterfly, we required an extensive amount of data and testing. We actually had a public scientific workshop to address, and in fact, no, there

aren't any effects associated with the use of Bt corn or Bt cotton with the Monarch butterfly.

With regard to insect resistance as well as gene drift, we actually have in place management plans to manage it so that we won't have the kind of gene drift that could occur. Or in the case of resistance, we want to ensure that this technology lasts for a long time, and frankly, so do the growers. So do the companies, everyone wants it to last for a long time. So we have in place, in the case of pesticidal products, plans in place to make sure that the technology will last and insect resistance will not occur.

Mr. MARSHALL. Just as a brief follow-up, if I had to pick one organization or publication or expert to go to to listen to a little bit of naysaying here, what organization, publication, or expert would either of you consider to be, you know, reasonable or credible? You know, there are lots of nuts out there that I don't want to waste my time with, and so can you identify somebody or entity or publication that is sort of credible and sort of a naysayer?

Dr. CRAWFORD. What we can do is provide a little bibliography and rank it. For recent reports on this, there have been three or four that are very good that present, you know, the possible reasons for the trade disputes and some assertions that some of these are science-based. And you know, they deconstruct it in a neutral way. We actually can supply you, I think, with those reports, and we will do that within 10 days' time, of course.

Mr. MARSHALL. Thank you very much. Thank you, Mr. Chairman.

Mr. LUCAS. And the Chair wishes to reassure the gentleman from Georgia that there will be all perspectives. The view of this is a beginning of a series of hearings on biotechnology so as to bring the members of the subcommittee and Congress up to date as to where we stand, the procedures, and the processes we go through. And then we will broaden our base and look at it from all perspectives, but building this well of knowledge. So that we have an understanding of some of the very complex procedures these gentlemen or agencies go through would seem to be the foundation-building part of the program. But we will have lots of fun before this is over, I assure you.

I will now turn to the gentleman, Mr. King.

Mr. KING. Thank you, Mr. Chairman.

And I have a broad question, and I would direct it to Mr. Johnson, who I happened to notice referenced the future in the horizon, so you are my designee for clairvoyance this morning. And just several parts to the same question, and I would really ask all of your attention to this is that looking at what is going on in the world and the resistance that is there in the European Union and the resistance there among some of the environmental groups. If you just fast forward in your mind a generation or so, and just say if politics and logic lost this public relations contest here between GMO products and the more organic version that they are promoting in other parts of the world. Can you envision a world 25 years from now that doesn't include GMO products? And if you can, then what would the impact be on nutrition, health, and population?

Mr. JOHNSON. Well, let me turn to my crystal ball and see, at least hazard a response. Certainly, as having been involved with

this technology for most of its life, and certainly as I look forward I really don't see a world that is void of this technology. I think that this technology has established its roots in a number of areas from whether it be drugs or cosmetics or in our case, pesticides or other kinds of uses. So as I look to the future, I see that the technology will be there. And I think one of the driving reasons for that is really the benefit.

And let me just talk about it from a human health environmental standpoint for a moment. In the case of Bt cotton or in the case of the newly registered Bt corn rootworm insecticide, what we see in the case of the Bt corn rootworm insecticide is a reduction of about seven and a half or eight million acres of insecticidal treatment or use of chemicals, and in fact, some fairly harsh. They work. If used properly, they don't present a risk to human health or the environment, but nonetheless, what we see is a significant reduction in that use. In the case of Bt cotton, again, we see a significant reduction in classical chemical use. And what does that mean? Well, certainly for workers who are handling the material, it is safer. Certainly from an environmental standpoint, there is less environmental loading. And certainly from a food safety standpoint, you are replacing a protein that is readily digested, just like other proteins, from a chemical. And so I think with the kind of benefits that we are seeing now and the kind of benefits that this technology holds for the future, I see the world embracing this technology, I would certainly hope sooner rather than later.

Mr. KING. And should the world not embrace this technology, would you concede that the impact on the nutrition health and population, it would limit the population of the earth and we wouldn't be able to sustain the requirement to feed the population that is growing?

Mr. JOHNSON. Well, I think that certainly it could have that kind of an impact, although very difficult, you know, to predict at the moment.

Mr. KING. Then it is difficult to predict, but this is, I think, a hypothetical question and I offer anyone to answer. And that is that if we can sit here in this panel and foresee and realize the very beneficial nature of GMO products and the essential nature of it that in order to provide the quantity and the quality of the food that we will need in the future, the people who are in opposition, does anyone want to speculate on what they envision the future to look like if they get their way?

Dr. CRAWFORD. I don't know what motivates them, but what I see is a world where there would be more hunger. Some time between 2020 and 2050, as you know, we are going to have 2 billion more people. There is hunger today. There will certainly be more without bioengineering food crops, also as a possibility of having geographical problems like redrawing the maps, because as deserts increase, we need crops that can grow in desert type conditions, as humidity increases, whatever happens with the changing weather patterns, which we know will be coming. If we had the flexibility that we have with biotechnology, we can perhaps meet that. And it is still possible in this world to have something like the potato famine of the mid-19th century. If biotechnology is allowed to continue, and it must be in my view, then we will have the capability

to deal with something like that, if not overnight, within a few days rather than the 20 or 30 years it might take to rebreed Irish potatoes or perhaps yams in Africa, rice in other areas of the world. Much of the world now depends on a staple crop for 50 percent or two-thirds of its nutrition.

The other thing, as we learn more about nutrition, finally, I think we would have more nutritional diseases without this. Once you understand nutrition, you have got to get, as you know, a nutrient-dense diet in order to take advantage of that. It is also possible we can modify. If things turn out to be the case like lycopene, which is in tomatoes preventing prostate cancer, for example, it can be included in some sentinel foods and improve that situation with bioengineering. I can not help but conclude that nutritional diseases of all sorts will be diminished.

Mr. KING. Thank you very much. Thank you, Mr. Chairman.

Mr. LUCAS. The gentleman's time has expired.

The Chair turns to the gentleman from North Carolina.

Mr. BALLANCE. Thank you, Mr. Chairman.

I am sort of like Mr. Marshall in this area, but I know there is some skepticism in the community and in America and around the world. And Dr. Crawford, I believe, gave testimony that you are not aware of any bioengineered plant food that is subject to FDA jurisdiction that is on the market that has not been evaluated by FDA through the current consultation process. In other words, although the current pre-market clearance process for biotech products is voluntary, the companies have always submitted to it. Is that the case?

Dr. CRAWFORD. Yes, we believe that to be the case. And we are not aware of any company that has not done that. I mean, I don't think it would be in anyone's best interest for that to happen. I don't think it is going to happen. If it does and the product posed some threat to the American people, then we can use the full force of our authority to protect the food supply to take advantage of that situation and interdict it from the market. And we wouldn't hesitate to do that. We would go to the American people and tell them, you know, the product isn't approved. It holds some threats to their health, and don't eat it.

Mr. BALLANCE. And of course the natural question that comes to mind is if that is the case, why has not FDA pressed ahead with this proposed rule to require that the pre-market clearance become mandatory?

Dr. CRAWFORD. We have a proposed rule, as you may know, that is on the books. We received comments on that rule. It was proposed a little over 2 years ago. We received 115,000 comments on it to date, and we are evaluating those. However, since the current system is working so well and since there is no public health reason to impose the mandatory requirement, it is not a high priority for FDA to finalize this rule at this point.

Mr. BALLANCE. Well, I started out with the idea that there is skepticism and would not a mandatory system silence those skeptics?

Dr. CRAWFORD. Well, I don't believe it would change. I mean, you know, I am not an expert in that particular area. But I don't believe it would change any minds, because if this system is working

and if we have been consuming these kinds of products for 10 years without any adverse events, including no recalls, whereas in the traditional food supply we have had adverse events, and we have had multiple recalls. If there is skepticism, I don't think this would be the answer to it.

Mr. BALLANCE. All right. Thank you, Mr. Chairman.

Mr. LUCAS. Thank you.

And the Chair turns to the distinguished chairman of the full committee who has been able to participate with us today. Any questions you might have, Mr. Chairman?

The CHAIRMAN. Thank you, Mr. Chairman. I first want to thank you for holding this hearing and continuing to press this committee's interests in biotechnology. This is a very, very important aspect of the future of American agriculture and I would argue the future of world agriculture and the ability to feed the world. I would follow-up on the comments, I think, of Mr. Johnson regarding the wide acceptance of biotechnology and safety, its advisability in the scientific community and the medical community not just in the United States, but around the world.

Earlier this year, I had the opportunity to meet with scientists at a biotechnology research facility in Belgium. And while they would not want to be on the record sharing with their political representatives the views that they hold, they did share them with me, and that is one of great frustration that ignorance and emotions and, in some instances, hysteria have rule in Europe and in some other parts of the world in this area. And it is clear that that frustration is holding back their ability to solve a great many problems that they had some very unique and novel ways of doing it. And instead, their talents have been channeled into the area of determining how to detect genetically modified organisms in products that might be shipped to them by the United States and elsewhere in the world as they get ready to enact a solution to the challenge that we have made to their moratorium, the solution being a labeling and traceability requirement that may be more onerous than the current ban, because it will make it more difficult to export non-GMO products. And we have consistently maintained our desire not to force anybody to eat anything that they don't want to eat but to simply have the opportunity to put these products on the shelves in Europe and elsewhere around the world and let them sell themselves for their environmental benefits, their nutritional benefits, in some instances, the longevity of the product, the taste quality of the product, and others as well as the cost will very well, I think, dictate the future course if we do get a fair shot there. I think the best thing we can do to continue to press ahead with that is to continue to do the work that all of you do to make sure that the American public, which has widely accepted and used these products very safely, I would note, for many, many years, that that confidence remains high and that we bring new products to the market as they are ready to be brought to the market, but continue to have an open process that people can review and see the data that is available, the studies that have been done. And with the assistance of responsible news media organizations, get the word out that these products are not only safe, but they are extremely beneficial in a wide variety of ways.

I would like to follow-up on the question asked by the gentleman from North Carolina to Dr. Crawford in a question to Mr. Hegwood. As a result of the response that we got there, I wonder, we understand that the FDA has recently published a notice in the Federal Register indicating that a decision on issuing a final rule on premarket notification would not be made for at least the next 12 months. As part of USDA's regulatory review, is it feasible for the Animal, Plant, and Health Inspection Service to formalize a consultation process with the Food and Drug Administration to ensure that the FDA is notified of the availability of an agricultural biotechnology product prior to its entry into commercial markets?

Mr. HEGWOOD. Well, we have a system now for ensuring that we have early discussions with both EPA and FDA at the field trial stage. Whether we would take that a step further, as I believe you are suggesting, is something we could certainly look at in the context of the ongoing review we are having of our regulatory system within the interagency process. It may be a way that we could address that issue.

The CHAIRMAN. Well, thank you. Would you review that suggestion, which is not mine alone, but others have put that forward as well, and let the committee know whether you think that that is something that you could pursue with FDA to help advance this process?

Mr. HEGWOOD. Yes, sir. We will do that.

The CHAIRMAN. Thank you very much. I appreciate it.

Mr. Chairman, I ask note that we had a little opportunity to advance information about biotechnology going on just as your hearing was beginning with a delegation from Brazil. And that is why I was late getting to the hearing, that came to join us and speak with us specifically about this issue. They have quite an interesting conflict in Brazil. They are using our biotechnology products, in some instances without paying the royalties on them, I would note, while at the same time they have laws banning the use of those products in Brazil and have, because they have now produced over a billion acres of, in particular, soybeans, created a temporary moratorium on the imposition of their law so this current year's crop can get into play in the world market notwithstanding their own laws and concerns about the issue. And we shared with them our concerns about that policy, but also our appreciation for their coming here to learn more about this issue and about biotechnology. And I think we are taking the right steps to build more consensus with that major exporting country. And I think since we have been joined by Argentina and Canada and Australia and a number of other countries in pursuing this issue with the World Trade Organization, the signs are increasingly positive that the major exporting countries will ultimately join us on this issue and that way I think make it far more economically attractive to create and market these products. And that hopefully will hold.

So I thank the chairman for allowing me to participate today.

Mr. LUCAS. Thank you, Mr. Chairman.

And now the Chair turns to Mr. Case.

Mr. CASE. With that announcement, I will start.

First of all, I just want to endorse the chairman's comments, thanking the subcommittee Chair for this hearing, and the series

of hearings promised. I think this is an issue that the more we talk about it, the better it will be for everybody. I also want to thank the subcommittee Chair for his response to my colleague from Macon's request for the opinion of the other side, because I certainly think that that is valuable for us to listen to people that do have concerns with the testimony that was given. And I think as we do that, we are going to get to the bottom of this. I am not sure we have gotten there. But I certainly, as one Member, want to get to the bottom of what are the realistic risks, if any. And what can we do about them and what is really an opposition for reasons other than legitimate concerns over plant or animal safety, for example, just basic issues of trade? I think as we listen to others, we will be able to isolate those issues.

Let me just say that I think, if I am understanding the issues correctly, we have really got two issues and two government responses. The first has to do with human health, the health of humans because they are consuming bioengineered foods or drugs manufactured by bioengineering.

The second is environmental and plant health. Let me focus on the latter, because looking at it through the lens of my own District, as most of us start to do, the opposition that I hear in my District tends to be more focused on is bioengineering going to upset the balance of the environment, which is a particularly sensitive issue in a place like Hawaii that has the highest percentage of endangered plant species in the world, as I recall, and where we have specialty crops that have gone through a very long history of their own kind of bioengineering to get themselves to a perspective of being able to produce what we want. Coffee is the perfect example in Hawaii. There are about 100-plus years worth of making coffee, and the coffee farmers are scared that the introduction into Hawaii of bioengineering research in other crops, not in coffee, but in other crops is somehow going to crossover and interfere with the coffee crop. And the same thing could be said about other crops in other areas.

So I think my question is more to APHIS than anybody else, Mr. Hegwood. The permits that you ask for, that you require, they are not optional like FDA, right? They are mandatory, the field testing and deregulation permits? Well, first, I want to get a sense of why are those permits not so much approved as rejected? And what are the risks that are presented by those that you try to stop by those permits and that you do stop? And what are the practices that somebody asks you to approve by permitting that you say no to? First of all, let us just start. How many of those permits are actually disapproved? What percentage, just in round figures? Is it like, you know, 50 percent or 1 percent or less than 1 percent or what?

Mr. HEGWOOD. OK. About 8 percent are disapproved.

Mr. CASE. And why are they disapproved? Are there categories of reasons where it is just pretty obvious that the risk exists that the permit is designed to protect against?

Mr. HEGWOOD. I think, in many cases, they are disapproved because confinement procedures are not adequate.

Mr. CASE. I am sorry, confinement?

Mr. HEGWOOD. Confinement procedures to prevent——

Mr. CASE. So isolation of the bioengineering crop from the general environment?

Mr. HEGWOOD. That is right. The primary risk that we are concerned about is out-crossing. It is pollen flow in some form. And so——

Mr. CASE. Within a crop or cross-crops or do you just not worry about the cross-crop thing?

Mr. HEGWOOD. We do worry about cross-crop contamination, so we would look at that as well as out-crossing from one corn field into another or cross-contamination as well into other crops. And so if the confinement procedures do not meet our standards, and those standards are developed on a product by product basis in consultation with the state regulatory officials, then we will not approve the permit.

Mr. CASE. Now is there another significant category of reasons to deny a permit, or is it pretty much all cross-crop confinement procedures? For example, are there certain crops that you are just not going to put next to other crops, period or——

Mr. HEGWOOD. That is a consideration. And as we move into the next generation of products, such as plant-made pharmaceuticals or industrials, that becomes even more of a consideration.

Mr. CASE. OK. One final question because I am about to run out of time. I don't understand the enforcement mechanisms. Is it a self-enforcing thing? I noticed you had testimony along the lines of a particular situation that came about and there was a consent decree and there was a $250,000 fine. And I have no idea whether that is, you know, reasonably related to the crime, if I can put it that way, but do you actually go out and enforce these permits or are they self-enforcing and when there is a violation, then there is an enforcement procedure? Is there a regulatory aspect to this that APHIS goes out and says, "Hey, are you complying with these permits?" And do you think that is adequate or resource-wise for the prevention of the risk?

Mr. HEGWOOD. We inspect every field test permit site at least once a year. And in the case of pharmaceuticals and industrials, much more frequently than that. And we also do follow-up visits in the succeeding years to make sure that, for example in the case of corn, that there are no volunteer plants growing in a field test site from the previous year. So we have very rigorous enforcement requirements, and we consider that an integral part of the regulatory process.

Mr. CASE. Thank you very much.

Mr. LUCAS. The gentleman's time is expired.

The gentleman from Nebraska, Mr. Osborne.

Mr. OSBORNE. Thank you, Mr. Chairman.

Just a very short question. It may take a while to answer. But there has been quite a bit of discussion about a new variety of biotech wheat. I wondered if you could inform us as to what the different agencies have been doing, how far we are away from some type of approval and what is going on with this particular issue? This is a question for, really, all of you.

Mr. HEGWOOD. We have received an application for a biotech wheat variety, I believe it was this past fall, that we first received the application. We have been reviewing it. The first review we

make is for the adequacy of the data that is presented and have we responded to the company? So we are in the process now of preparing to respond to the company as to whether their data is adequate to proceed with deregulation. And once we have adequate data to support a decision, only then would we be in a position to make a determination to deregulate the product. But at this point, we have not informed the company. We have not made a determination of whether we have the adequate data. And we will be doing that very shortly, but I think we are not looking at an immediate decision. I don't think there is any expectation that there would be a decision on deregulation for the next planting season.

Dr. CRAWFORD. Well, the FDA obviously follows APHIS's lead, USDA's lead. And we have also been informed of the crop. We would be in an evaluation mood, but it would not be until APHIS reaches its determination before we finally inform the company about the marketability.

Mr. JOHNSON. And likewise from an EPA perspective. Although in EPA's case, we are additionally concerned about what pesticides that may or may not be able to be used on the particular crop. And so we need to look at the pesticide product itself, the chemical itself, and to make sure that we wouldn't have any unintended consequences associated with the chemical use on the particular genetically engineered. But we are in the same position as USDA and FDA.

Mr. OSBORNE. It seems to me that sometimes when we are dealing with biotech, there are really two issues. One is the science, and then second is public perception. And if you get one out of it or the other, it seems like you have a problem. Particularly, it is the science is ahead of the perception issue.

And just a general question again. Do you gentlemen have any thoughts as to how to prevent some of the issues that we had with Star Link and other issues where we were not really very well coordinated in how the whole topic was handled?

Mr. JOHNSON. I can certainly start, Mr. Osborne. On the case of Star Link, certainly starting from the beginning that the way the pesticide law is constructed, it actually allows for the so-called split registration, in other words to allow a pesticide, whether it is a chemical or a product of biotechnology in the StarLink case, to be used on and get into animal feed but then not to be allowed to be used into human feed, if you will. In the case of Star Link, the company availed itself of that ability of the law. Certainly our experience with the Star Link situation showed that even though it is legally able to be done, as a policy matter, we are not granting a split registration for the very reasons that we saw in Star Link.

I think the important thing to note about Star Link, a number of people view it as a failure of the system. In fact, I view it as a great success of the system, because the U.S. Department of Agriculture and the Food and Drug Administration and the EPA quickly stepped in to take control and actually manage the whole Star Link situation to get it out of the food supply. And so when we became aware of a problem in the case of Star Link, we took swift action, which was costly, fortunately, with the company's cooperation to deal with. And certainly as we consider future products, as

I said, we are not granting split registrations in the case of Star Link.

Dr. CRAWFORD. Yes, I agree. I think it was a success, from FDA's point of view, and the fact that there won't be split registrations will help us in the future. The key to it is always good communication between the three agencies that are represented here. And I believe we have that. And so I think we can learn some things from Star Link and some of these other episodes, but for the most part, what we learned is that the system works.

Mr. OSBORNE. Thank you, Mr. Chairman.

Mr. LUCAS. Thank you, Mr. Osborne.

One last question from the Chair. Could you expand for a moment on how the agencies are working together to expand APHIS's rule on plant-made pharmaceuticals to make it applicable also to the plant-made industrial products?

Mr. HEGWOOD. We have recently issued new guidance to the industry for field testing requirements for plant-made pharmaceuticals. We are in the process of developing an interim rule for notifications. Many of the industrial products are currently done under notification procedures rather than permitting procedures. And so the interim rule that we are working on would shift the field testing requirements for industrials to the permitting system so that we would have greater control over the field tests.

Dr. CRAWFORD. Yes, we also are evaluating with APHIS the procedures that would be used. We think that our system, you know, is active and also is sufficient to deal with this particular new industry. We would want to regulate it from a public health point of view so that it poses no risk or minimal risk to the population. But also, we would want to see in place regulations and procedures that would not unfairly disadvantage this industry, because we believe that this is a good modality in the future for producing pharmaceuticals and other products.

Mr. JOHNSON. Mr. Chairman, the same applies for EPA. In our case, instead of the pharmaceuticals, we are now seeing the development of industrial products, industrial chemicals, enzymes, and other kinds of materials. And so likewise, we are working with the Department of Agriculture and Food and Drug Administration to make sure that we have got a coordinated framework that ensures public health and environmental protection and at the same time doesn't inhibit a good technology and innovation.

Mr. LUCAS. The Chair has no further questions. Are there any other questions from any other member of the panel? Seeing none, the Chair wishes to thank the gentlemen for your insightful comments and to note that without objection, the record of today's hearing will remain open for 10 days to receive additional material and supplemental written responses from witnesses to any question posed by a member of the panel.

This hearing of the Subcommittee on Conservation, Credit, Rural Development, and Research is adjourned. And the Chair wishes to note that in approximately 5 minutes, the subcommittee will reconvene for a markup on House Resolution 1907.

[Whereupon, at 12:15 p.m., the subcommittee adjourned.]

[Material submitted for inclusion in the record follows:]

STATEMENT OF DAVID HEGWOOD

Thank you for the opportunity to be here today. I am pleased to provide the subcommittee with an overview of the Department of Agriculture's role in the regulation of products derived through biotechnology.

The advances made in recent years in this field have shown us quite clearly that biotechnology has the potential to improve existing products and create new ones capable of benefiting the environment, agriculture, human health, and the U.S. economy. In some cases, however, the advances made by researchers and biotechnology companies have also brought forth challenging new questions for regulators and a range of important concerns expressed by citizens, industry groups, and other stakeholders.

For these reasons, the Federal Government is playing an active role in ensuring that these new products are safely developed and field-tested. This is critical for reassuring industry, consumers, and other groups—both here in the United States and, increasingly, abroad—that biotechnology derived crops, animal vaccines, and other products will not harm agriculture, the environment, or human health. Consistent with the Coordinated Framework (51 FR 233302, June 26, 1986), USDA is working with the Environmental Protection Agency (EPA) and the Food and Drug Administration (FDA) to make sure that the United States continues to lead the world in the safe development and commercialization of genetically enhanced agricultural products.

REGULATORY OVERVIEW

For its part in this coordinated effort, USDA's Animal and Plant Health Inspection Service (APHIS), under the Plant Protection Act, regulates the interstate movement, importation, and field-testing and release of bioengineered plants, insects and microorganisms through permitting and notification procedures. APHIS' efforts help to ensure that transgenic plants and organisms do not have unwanted effects on U.S. agricultural health or the environment.

In other areas, APHIS regulates biotechnology derived veterinary biologics under the Virus-Serum-Toxin Act. The Agency is also evaluating its role in the regulation of genetically engineered animals, pathogens, and pests under the authority of the Animal Health Protection Act (AHPA), which was passed as part of the 2002 farm bill. The AHPA enables APHIS to address any pest or disease risk posed to livestock, and we continue to coordinate with other agencies, including FDA and EPA, that share regulatory responsibility in this new arena.

In general, APHIS' field testing requirements for - regulated plants are designed to prevent the unintentional environmental introduction, whether by pollen movement, seed or grain commingling, or other means, of any protein or trait produced in these plants that would present a risk or potential risk to agricultural crops or the environment. APHIS has a permit system for the field-testing of genetically engineered crops on a case-by-case basis. Companies that wish to field test such crops must submit applications, with information about the plant variety being tested, the purpose of the test, how it will be conducted, and the specific confinement conditions taken to prevent the escape of pollen, plants, or plant parts from the field test site and prevent persistence in the environment. Applicants must meet or exceed the basic requirements for planting, pollination control, and the harvesting and shipping processes set by APHIS. These basic requirements are specific to each plant variety, and we continually evaluate them to ensure that the latest scientific evidence is taken into account. After reviewing the information contained in the permit application, we may require that applicants modify their proposals to include additional conditions.

APHIS also has a streamlined permitting process, called notification, in place. Most of the field tests carried out in the United States are done under notification. The notification process expedites approvals for field-testing for certain types of low risk plants that APHIS has considerable experience in regulating. Under the notification procedure, the regulated article to be field-tested must be a plant, and the genetic modifications to that plant must meet established eligibility criteria. When APHIS receives a notification, it is typically reviewed within 10 to 30 days, forwarded to State officials for further review, and then returned to the applicant as either acknowledged or denied.

I want to emphasize again that APHIS is committed to ensuring that State interests are fully considered and accommodated in the Agency's biotechnology field test permit application and approval processes. Before any field test can be undertaken in a given State, APHIS officials provide permit information pertaining to the proposed field test to their counterparts in that State for review and concurrence. If

a particular State has concerns about the confinement measures described in the documentation, APHIS works with that State to address the outstanding concerns and add any additional conditions the State deems necessary to ensure that the field test can be conducted safely.

We believe that these customized field testing requirements, when fully met by permit holders, are capable of confining these plants to test sites. To encourage and enforce compliance with these requirements, all field test sites are subject to APHIS inspection. Field test sites under permit are inspected at least once during the growing season to confirm that the permit holder is meeting all the conditions specified in the field test permit. Should an APHIS inspector find that a permit holder is not complying in full with the permit requirements, APHIS would require the holder to come back into compliance with the permit requirements and, depending on the severity of the problems, the Agency could also initiate an investigation and possible enforcement procedures.

After successfully completing the field-testing stage of a new plant variety's development, a permit holder can petition APHIS to deregulate the biotechnology crop. In support of this petition, the permit holder must submit further information on the results of the field-testing, in addition to information attesting that the plant poses no risk to agricultural crops or the environment. In considering the petition, APHIS carefully reviews the data submitted by the permit holder, and also weighs other pertinent scientific studies and information. When APHIS deregulates a biotechnology-derived plant, it does so because the plant poses no pest risk to other crops or plants. The deregulation process requires that APHIS publish a Federal Register notice thereby making the decisions documents available to the public. Once APHIS deregulates a particular biotechnology product, the company must still comply with applicable FDA or EPA requirements prior to marketing. In addition, APHIS can bring a product back under regulation at any time if the Agency becomes aware of evidence indicating that the product may pose some sort of plant pest risk.

The administration, through the NEC's Agricultural Biotechnology Working Group, is addressing regulatory challenges posed by rapidly developing science and how this science is being applied to potentially new products. For example, in August 2002, the White House's Office of Science and Technology Policy (OSTP) published a notice in the Federal Register relating to the inadvertent and low-level presence of varieties being developed for food and feed purposes that have not completed applicable agency review. In this Federal Register notice, APHIS proposed to update requirements for field-testing of genetically engineered plants. The USDA, EPA, and FDA have received comments regarding the Federal Register notice and are in the process of developing appropriate responses. The Working Group is now looking at regulatory challenges posed by plants genetically engineered to produce pharmaceuticals and industrial chemicals.

To further coordinate regulatory efforts, as well as increase the transparency of the decision-making process, APHIS is working with EPA, FDA, and several other involved Federal agencies on the creation of a unified government website regarding new biotechnology products. Once operational, this website will allow stakeholders and other interested parties to view basic information on the products and, when appropriate, what determinations have been made by Federal regulators. The website is currently in the final stages of development and should be launched later this year.

USDA Research Initiatives

USDA has two major research initiatives with regard to biotechnology risk assessment and risk mitigation. The longer running program is the Biotechnology Risk Assessment Competitive Grants Program (BRACGP), established in 1992 to comply with language in the 1990 farm bill. The BRACGP has played a central role in identifying potential risks involved in the development and release of certain bioengineered products. Funding for these grants typically extends for 2 to 3 years.

The second research initiative is housed within USDA's Agricultural Research Service (ARS), and is designed to complement the BRACGP. In general, ARS provides funding for research on biotechnology risk assessment and risk mitigation, enabling the collection of data over longer periods of time. Officials with APHIS, EPA, and the FDA benefit from receiving such comprehensive, unbiased data from ARS, and can use this information to make adjustments to existing regulations or other field test requirements. The ARS peer review process ensures that the research projects undergo intensive scrutiny.

PHARMACEUTICAL PLANTS

APHIS subjects pharmaceutical crops to more restrictive confinement conditions than most genetically engineered crops. Due to the relative newness of this field of biotechnology, APHIS takes a proactive approach to regulating field tests of so-called pharma crops. Again, working closely with FDA and EPA, APHIS officials monitor new scientific developments and review its regulations to ensure that the Agency's requirements are appropriately targeted to address any relevant agricultural, food safety, and environmental risks associated with pharma crops.

APHIS and FDA share responsibility for regulating pharmaceuticals produced in plants, from the field-testing stage through the final approval of a pharmaceutical product. APHIS believes its customized field testing requirements for pharma crops, when fully met by permit holders, coupled with the Agency's increased inspections and oversight, provide a solid basis for the safe field testing of pharmaceutical plants in the United States.

On March 10, 2003, APHIS published a notice in the Federal Register indicating new measures prescribed by the Agency that apply to the field-testing of pharmaceutical plants, starting with the current 2003 growing season. Included are requirements for mandatory recordkeeping; increased buffer zone distances around field trials; dedicated equipment and mandatory training for field personnel; and, as mentioned earlier, increased frequency of field inspections conducted by Agency officials. The comment period on the notice just closed on May 9, and we have begun to review all the comments we received.

In addition to administering regulations regarding bioengineered plants, APHIS has also worked with the FDA to develop a draft guidance document for companies that use such plants in the production of biopharmaceuticals. Among other things, the document provides companies with guidance in addressing environmental issues such as containment during field-testing, and other human health and safety issues. The document includes an outline of plans to conduct formal environmental analyses of pharmaceutical crops when commercial production is near. The public comment period for this document closed on March 7, 2003. APHIS and FDA are currently reviewing the comments received.

PRODIGENE, INC.

The situation involving violations at ProdiGene, Inc.'s field test sites highlighted the effectiveness of APHIS' routine compliance inspection procedures, demonstrating that the Federal oversight system can detect potential problems and respond swiftly and appropriately to safeguard U.S. agriculture and the domestic food supply.

Last fall, at sites in Nebraska and Iowa, APHIS found volunteer corn plants that were descendants of the previous year's cornfield tests. The presence of these volunteer plants was a violation of ProdiGene's permit conditions. APHIS, in cooperation with FDA and the State of Nebraska, took appropriate action to keep the product in the warehouse and out of the food supply. In addition, APHIS signed a consent decision with ProdiGene. The consent decision included a considerable monetary penalty, in addition to new requirements that ProdiGene will need to follow during field tests of its bioengineered crops. APHIS will also be monitoring ProdiGene's future field tests very closely and will take further action if necessary.

BIOTECHNOLOGY REGULATORY SERVICES (BRS)

In June 2002, APHIS established a new biotechnology unit to consolidate and better coordinate its services and activities in this area. The new unit, Biotechnology Regulatory Services (BRS), is responsible for programs focusing on both plant-based and animal-based biotechnology.

By consolidating policy and operations into one unit, APHIS is able to bring greater focus to its domestic and international policy coordination and development and its risk assessment, permitting, and compliance activities. The creation of BRS also allows APHIS to communicate more consistently to State regulators and our other stakeholders and ensures that USDA continues to develop appropriate regulatory policies to address emerging biotechnological issues and challenges.

We plan to strengthen BRS' inspection and compliance unit. As mentioned above, since the ProdiGene, Inc. incidents, APHIS has increased its oversight of field tests involving plants engineered to produce pharmaceutical and industrial products. We conducted 305 inspections in 2002 and we estimate that the Agency will about double that number of inspections during this growing season. APHIS will also significantly increase the number, quality and rigor of audits it conducts of permit holder records.

As one of its first initiatives, BRS has established an Office of Science to ensure the continued enhancement and credibility of APHIS' biotechnology regulatory program. Working with the regulatory and policy staffs, this office will help to funnel the latest scientific information into policy, regulation, and risk-assessment efforts. We expect that personnel with the Office of Science will also form strong working relationships with their colleagues in academe and the private sector, providing current information for APHIS decision makers and ensuring Agency personnel are using the most up-to-date information, protocols and assessment procedures.

Finally, BRS officials are responding to recommendations made in reports issued in 2000 and 2002 by National Academy of Science (NAS) review panels. As requested in the 2002 farm bill, APHIS, along with FDA and EPA, is preparing a report summarizing our current biotechnology regulatory programs and the potential directions these programs may take in the future. Consistent with several recommendations made by the NAS review panels, APHIS officials are continuing with steps to improve the Agency's risk assessment process, in addition to all of the safeguards built into the biotechnology regulatory program.

Thank you again for the opportunity to be here today.

STATEMENT OF STEPHEN L. JOHNSON

Good morning, Mr. Chairman and members of the subcommittee. I am pleased to appear before you today to discuss the Environmental Protection Agency's (EPA) role in the assessment and regulation of products produced through biotechnology. I welcome the opportunity to participate on this panel and explain what the Agency is doing to regulate biotechnology products. We are working closely with our partner agencies, the U.S. Department of Agriculture (USDA) and the Food and Drug Administration (FDA) to ensure that crop plants created using biotechnology, and food from such plants, are safe to both people and the environment.

Biotechnology holds great promise. For example, it can reduce our reliance on some older, potentially more risky pesticides, while also reducing potential risks to farm workers and the environment. Given these and other potential benefits, the Agency is committed to ensuring that our regulatory decisions are based on rigorous scientific information, the highest scientific standards, with a high degree of transparency to ensure our decisions are available to the public for understanding and oversight. By following these principles, our program ensures the protection of public health and the environment, while promoting consumer confidence in our regulatory decisions. Biotechnology is a rapidly evolving field, and requires that the Federal Government's regulatory program similarly advance to ensure the continued protection human health and the environment. The Agency believes that regulated biotechnology products are safe, provided they are used according to the approved labeling. Given our intellectual and scientific investment in regulating biotechnology, the Agency stands ready to meet the future challenges.

COORDINATED FEDERAL FRAMEWORK

In the early 1980's, companies began to apply the techniques of bioengineering to agriculture for eventual commercial use. Also at this time, the Federal Government began to evaluate its options for regulating products created using biotechnology. In 1986, the Federal Government released a document entitled: "Coordinated Framework for Regulation of Biotechnology" which laid out the broad approach to regulating biotechnology products. In summary, the products of biotechnology would be regulated under existing statutes and in a manner similar to the regulatory approach used for products not produced through this technology.

The Framework established an approach to regulating the products of this new technology based on the characteristics of the products and the specific use of the product, not the process used to create it. Rather than seek new legislative authority, the Federal Government concluded that it could appropriately regulate these products using existing laws, but also recognized that, in some cases, new regulations would be needed. Thus, products that are intended to be used as pesticides are regulated under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the Federal Food, Drug and Cosmetic Act (FFDCA). Also, under the Toxic Substances Control Act (TSCA), EPA reviews bioengineered microbes and the substances they produce when the genes come from a different type of microbe. The Framework has been reaffirmed by several administrations, including the current one, and current efforts are aimed to make the coordination between EPA, FDA, and USDA even stronger, while ensuring a comprehensive and seamless regulatory system.

STATUTORY FRAMEWORK

Under the Framework, EPA regulates products under FIFRA and section 408 of the FFDCA; this includes bioengineered (and naturally occurring) microorganisms with pesticidal action as well as products produced by plants that act within the living plant as pesticides to protect the plant. Any remaining residues of these pesticides are regulated under FIFRA and the FFDCA. The products produced by plants which are intended to act as pesticides, along with the genetic material necessary to produce these substances, are called plant- incorporated protectants or PIPs.

EPA proposed two different sets of rules for these two different types of products. In 1992, the Agency proposed rules tailoring the experimental use regulations for microbial pesticides. EPA finalized rules dealing with field testing of microbial pesticides in 1994. Similarly, EPA proposed an approach to PIPs in 1994, and major portion of these regulations were finalized in 2001. These rules formalized regulatory procedures for plants bioengineered to exhibit pesticidal traits. PIPs created through conventional breeding were exempted from regulation. A National Academy of Sciences study in 2000 urged, after examining the existing knowledge, EPA to reconsider some of the PIP exemptions originally proposed in 1994. In 2001, EPA asked for additional public comment on these specific exemptions and the NAS analysis. EPA is currently considering comments received, the NAS analysis, and the record on the scientific merit and potential risks associated with granting these exemptions.

THE BIOTECHNOLOGY PROCESS

To fully understand our regulatory approach to PIPs, some basic information on biotechnology may be helpful. EPA's jurisdiction under FIFRA is limited to pesticides. For example, the sale of a plant that has been bioengineered to resist insect damage would be subject to FIFRA, whereas a plant engineered to resist drought would not. Such products come under our authority because the substance produced by the plant is intended to function as a pesticide by affecting a pest. In this latter instance, a substance produced by the drought resistant plant may result in, for example, deeper roots to enable the plant to access more water reserves. This bioengineered plant would be subject to USDA authorities, and any food or feed obtained or produced from such a plant would be subject to FDA authorities.

Up until the last quarter of the twentieth century, growers have relied on plant breeders to provide them with hardier and more disease-resistant crop varieties. This is done primarily through plant breeding and transferring pollen from one variety of crop to the flower of another variety, or mating a crop plant with a wild or related plant to produce offspring with the desired trait. It is the way that we got bigger roses and more robust tomatoes.

In the early 1980's, scientists began to move single genes selectively through biotechnology techniques. The transfer of desired traits could now be accomplished more broadly and more rapidly. Science is at the point now where genes can be moved between unrelated species. In the case of PIPs, scientists alter plants to produce pesticidal substances from any source, for example, from another plant, a bacterium or virus, etc. The most well known example is the bacterium Bacillus thuringiensis, or simply Bt. This bacterium, when sprayed on plants, is toxic to certain types of pest insects that feed on the plant. Through the process of biotechnology, scientists can remove the genes that produce the toxic protein from the bacterium and place them in, for example, a corn plant. The corn plant can now synthesize its own Bt protein and ward off pests on its own. No external spraying for the target pest is necessary.

EPA'S REGISTRATION REQUIREMENTS AND PROCESS FOR PIPS

EPA has been working with companies and individuals since the early–80's in developing a regulatory approach for pesticide related biotechnology products. In developing our approach, EPA has held numerous public meetings with extramural panels of scientific experts; e.g., the Agency's Biotechnology Science Advisory Committee, the FIFRA Scientific Advisory Panel, the Office of Pesticide Programs' Pesticide Program Dialogue Committee, and with interested stakeholders at a number of public hearings and workshops throughout the country. Through this process, the Agency has developed robust regulatory and scientific standards for biotechnology products going through the registration process.

Specifically, a potential registrant typically comes in for a meeting with our scientific staff, at which time we decide upon the appropriate data requirements to support the Experimental Use Permit (EUP), the tolerance or tolerance exemption,

for the full commercial approval and registration. The studies done under the EUP are used to obtain the data necessary to support the application for the full registration. Once the Agency receives a complete package for a new PIP active ingredient, it typically takes about 18 months for the Agency to review the data and reach a registration decision.

For the PIPs products EPA has registered to date, we review data in five categories: product characterization, toxicology, non-target organism effects, and exposure and environmental fate, and resistance management. Product characterization includes reviewing the source of the gene and how the gene is expressed in a living organism, the nature of the pesticidal substance produced, modifications to the introduced trait as compared to that trait in nature, and the biology of the recipient plant. For toxicology, an acute oral toxicity test of the pesticidal substances on laboratory animals is required. At times, it has not been possible to make enough of the substance for testing purposes in the plant itself so EPA has allowed the exact same protein to be produced by bacteria and used for the testing.

It should be noted that to date, all of the PIPs reviewed by EPA are protein based. For protein based PIPs, EPA requires a digestibility test where the amount of time it takes for the protein to break down in gastric and intestinal fluids is determined. This information is relevant to a determination of the potential of the protein to be toxic or an allergen. EPA and FDA are working together on this issue. Currently, for an allergenicity assessment, EPA requires digestibility test, tests for heat stability, and a comparison of the structure of the protein to the structures of known food allergens.

For ecological effects, EPA examines the exposure and toxicity of the PIPs to non-target organisms, such as wildlife and beneficial insects. These tests are unique to the crop and pests involved. For example, during the review of the Bt- potato, a test of potential effects of the introduced protein to lady beetles was conducted and showed that there were no adverse effects to these predators of the pesky Colorado potato beetles. For Bt-corn, tests were conducted on the potential effects on fish because field corn may be manufactured into commercial fish food. No effects were observed in the tests. Currently, monitoring of potentially affected organisms in fields planted with PIPs is also required. EPA also can evaluate the degradation rates of the proteins in soil and plant residues. If any concerns or questions arise from the testing, a second or higher tier of testing is required to allow EPA to more thoroughly evaluate the potential risks. EPA routinely consults with our Scientific Advisory Panel, the USDA, the FDA and others as we carefully evaluate the scientific and regulatory issues.

Currently, EPA has registered 11 separate PIP products. Ten of these products are for a Bt protein. The crops have included: potatoes, cotton, field corn, sweet corn, and popcorn. There have also been Experimental Use Permits issued for Bt tomatoes and Bt soybeans. The Agency has also established tolerance exemptions for pesticidal proteins from viruses that have been moved to plants like watermelon, cucumber, potato, and papaya. In 1998, EPA registered a PIP based on the potato leaf roll virus (PLRV) and a Bt protein. The Bt protein and the PLRV protein were combined to provide virus and insect protection.

In 2001, EPA completed a reassessment of all of the existing Bt registrations, to make sure that all uses were up to current regulatory and scientific standards. All stakeholders were encouraged to participate and the Scientific Advisory Panel was convened to peer review EPA's scientific findings. As a result, those Bt products that were reregistered were supported by the latest scientific data requirements and are being used under updated and more stringent regulatory conditions.

Recently EPA has approved two new products that should help farmers reduce reliance on chemical pesticides. The first product is a new version of Bt cotton with an additional pesticidal protein that is expected to improve resistance management. It should control more insect pests than the previously-registered Bt cotton product. The second is the first Bt corn product to control the most important corn pest—the corn root worm. We estimate that this product can reduce chemical insecticide use by 7.5 million acre treatments in the first 3 years of its registration.

OTHER CHALLENGES

EPA believes that these are promising times for advancing better, lower risk solutions to pest control needs. We believe that these products have great potential. However, the Agency is proceeding cautiously to ensure protection to all citizens and to our environment. At this juncture, I would like to turn the discussion to some of the other issues that have been raised and what EPA is doing to address them.

THE MONARCH BUTTERFLY

Back in 1999, the Monarch butterfly made headlines when researchers at Cornell University determined that immature Monarchs might be susceptible to pollen from some Bt corn plants. As a result of this information, EPA required registrants of Bt corn to undertake exhaustive and comprehensive studies to determine the toxicity and exposure of immature Monarch butterflies to Bt corn products. The results of these studies, which were published in the Proceedings of the National Academy of Sciences, have shown that none of the existing registrations have any effects on Monarch butterfly populations.

STARLINK CORN

When StarLink corn was registered in 1998, the data concerning the digestibility of the protein was insufficient to make a complete assessment on the potential for the protein to be a potential food allergen. EPA registered StarLink with restrictions designed to keep it out of the human food supply (such as allowing sales only to animal feed and industrial processors, and requiring buffer zones between non-StarLink corn). Despite these restrictions, the protein from StarLink corn was discovered in human food (taco shells). As a result EPA, FDA, and USDA worked closely together to both divert all corn containing the protein to non- human food uses and to ensure that corn seed for growers would be StarLink-free. Additionally, an assessment on the potential reports of allergenicity in people was conducted in cooperation with the Centers for Disease Control and Prevention (CDC). No incidents of allergenicity have been confirmed from the CDC investigations. The registration for StarLink corn has been cancelled. EPA meets regularly with FDA and USDA to monitor the success of the containment program for StarLink, and determine if any changes are necessary in the testing program for corn being used in dry milling. In order to assure that the StarLink situation does not occur again, EPA has instituted a policy of not approving registrations that are restricted to animal and industrial uses in crops people use for food.

INSECT RESISTANCE MANAGEMENT

The Agency has placed specific requirements on pesticide manufacturers to prolong the life of Bt pesticides, and delay the development of insect resistance. EPA's strategy to address insect resistance is threefold: (1) closely monitor and if resistance is detected, take immediate steps to mitigate any future potential for resistance development in the field, (2) implement restrictions to prevent resistance, and (3) continue research on the best techniques to prevent resistence.

EPA'S OTHER BIOTECHNOLOGY REGULATORY PROGRAMS

EPA also administers regulatory oversight over the commercial introduction of new microorganisms and the significant new uses of existing microorganisms under the authority of The Toxic Substances Control Act, also known as TSCA. This law gives EPA the authority to take action on "chemical substances" which may present an unreasonable risk of injury to health or the environment. TSCA's jurisdiction generally covers all new and existing chemical substances, except for certain products, including: pesticides, tobacco products, certain nuclear material, food, food additives, drugs, and cosmetics.

Under this framework, EPA has established procedures for the regulation of microorganisms that are products of biotechnology as "new chemical substances." The rule is designed to ensure that EPA can adequately identify and regulate potential risk associated with microbial products of biotechnology without unnecessarily hampering this important technology.

Under section 5 of TSCA, if a person wishes to commercialize a new microorganism, or plans to introduce such microorganisms into the environment for commercial research purposes, EPA requires a notification at least 90 days prior to commercialization and the submission of certain information. EPA reviews the information to determine whether the intended activity may present an unreasonable risk to health or the environment. Decisions on what action to take for each submission are based upon reviews by a multi-disciplinary team of scientists. This process determines if a new microorganism, when used under certain conditions, would not pose any unreasonable risk to public health or the environment.

Types of microorganisms that fall under TSCA are ones that are used in the production of industrial or specialty enzymes, e.g., detergent formulation, processing aid in the pulp and paper industry. These microorganisms are generally produced under closed systems. Microorganisms that are intended to be released to the envi-

ronment include ones used in bioremediation, biosensors or agriculture applications, such as nitrogen-fixing bacteria for increased yield in alfalfa or soybean production. Because TSCA specifically excludes pesticides and food, this program has few notifications with agriculture applications.

INTERNATIONAL ACTIVITIES

Biotechnology also holds great global promise, and the Federal Government is actively engaged in a wide array of international activities. Specifically, EPA participated as part of the U.S. delegation to the Codex task force to develop guidelines and principles for assessing foods derived from biotechnology. This international effort by regulators and scientists sets forth a set of principles and guidelines any country can use to assess these products.

EPA is also working on several international fronts in an effort to share data and foster collaborative relationships in various regulatory and scientific issues regarding biotechnology. EPA, in conjunction with USDA and FDA, was instrumental is establishing two workgroups with the Organization for Economic Cooperation and Development. These groups provide information useful to EPA as it performs risk assessments on products of modern biotechnology. EPA, along with other Federal agencies, has been developing a workable implementation of the Cartegena Protocol on Biosafety with the involved parties. We have also been involved in standard setting activities under the International Plant Protection Convention. In addition, EPA has been active in many bilateral exchanges of information and expertise. For example, we receive numerous international visitors a year who come to learn about our regulatory process. Some of these visitors are building their own regulatory structures and find our information valuable. Others come just to understand our risk assessment process so they can be more assured about eating foods derived from biotechnology and produced in the United States. We have also worked with U.S. Agency for International Development to provide information on how our regulatory process participates in ensuring the safety of domestically grown grain both for the public and recipients of USAID's food aid programs. All of these activities have been valuable to ensure the U.S. remains a recognized leader in regulating biotechnology products.

Thank you for allowing EPA to share its experience with biotechnology. The Agency's biotechnology program is based on five important principles: sound science, transparency in decision making, consistency and fairness, collaboration with regulatory partners, and building public trust. EPA believes that the regulatory system is based on the most rigorous scientific information available, is credible, is defensible, and will serve to protect the environment and public health, and can evolve to meet the important challenges that lie ahead. It is important that all parties work together to ensure the proper oversight and management of biotechnology so its considerable potential can be fully realized.

Thank you for the invitation to appear before your subcommittee. I will be happy to answer any questions you may have.

STATEMENT OF LESTER M. CRAWFORD

Mr. Chairman and members of the subcommittee, I am Lester Crawford, Deputy Commissioner of Food and Drugs. Thank you for the opportunity to testify today on the regulatory program of the Food and Drug Administration (FDA or the Agency) for foods derived from plants using the tools of biotechnology, also known as genetically engineered, or bioengineered, foods.

BACKGROUND

Within FDA, the Center for Food Safety and Applied Nutrition (CFSAN) oversees bioengineered plant products and ingredients intended for human consumption. Our Center for Veterinary Medicine (CVM) oversees bioengineered plant products used as animal feed or as an ingredient in animal feed, as well as bioengineered products used to improve the health or productivity of animals. My testimony this morning focuses on bioengineered plant products.

We believe it is very important for the public to understand how FDA is regulating the new bioengineered foods being introduced into the marketplace and to have confidence in that process. Therefore, I appreciate this opportunity to describe our policies and procedures.

First, let me state that FDA is confident that the bioengineered foods on the U.S. market today are as safe as their conventional counterparts. This conclusion was

echoed in both a 2002 General Accounting Office report and a report published in 2000 by the National Resource Council of the National Academy of Sciences (NAS). The NAS report stated, "The committee is not aware of any evidence that foods on the market are unsafe to eat as a result of genetic modification."

Let me also clarify that in the Federal Food, Drug, and Cosmetic (FD&C) Act, food is defined as food for man or other animal. So, when I talk about food, it also encompasses animal feed unless stated otherwise. FDA has reviewed the data on more than 50 bioengineered food products, ranging from herbicide resistant soybeans to a modified canola oil. To date, the evidence shows that these foods are as safe as their conventional counterparts.

In a 1992 policy statement on bioengineered foods, FDA announced that the Agency was "not aware of any information showing that foods derived by these new methods differ from other foods in any meaningful or material way, or that, as a class, foods developed by the new techniques present any different or greater safety concern than foods developed by traditional plant breeding." This 1992 statement and its scientific underpinnings still reflect FDA's thinking about bioengineered foods.

CROSSBREEDING, HYBRIDIZATION, AND BIOENGINEERING

Scientists have been improving plants by changing their genetic makeup since the late 1800's. Typically, this has been accomplished through cross breeding and hybridization in which two related plants are cross-fertilized and the resulting offspring have characteristics of both parent plants. In the breeding process, however, many undesirable traits often can appear in addition to the desirable ones. Some of those undesirable traits can be eliminated through additional breeding, which is time-consuming. Breeders can then further select and reproduce the offspring that have the desired traits. Many of the foods that are already common in our diet are obtained from plant varieties that were developed using conventional genetic techniques of breeding and selection. Hybrid corn, nectarines (which are genetically altered peaches), and tangelos (which are a genetic hybrid of a tangerine and grapefruit) are all examples of such breeding and selection.

Today, by inserting one or more genes into a plant, scientists are able to produce a plant with new, advantageous characteristics. The new gene splicing techniques are being used to achieve many of the same goals and improvements that plant breeders historically have sought through conventional methods. Today's techniques can be used with greater precision and allow for more complete characterization and, therefore, greater predictability, of the qualities of the new variety. They give scientists the ability to isolate genes and introduce new traits into foods without simultaneously introducing undesirable traits. This is an important improvement over traditional breeding. Any genetic modification technique, including both traditional methods and bioengineering, could change the composition of a food in a manner relevant to food safety. But because of the increased precision offered by the bioengineered methods, the risk of introducing detrimental traits is actually likely to be reduced.

FDA has found no evidence to indicate that ordinary plant deoxyribonucleic acid (DNA) or the DNA inserted into plants using bioengineering presents food safety problems. The small amounts of the newly expressed proteins are unlikely to change dramatically the safety profile of the plant as well. If safety concerns should arise, however, they would most likely fall into one of three broad categories: allergens, toxins, or anti-nutrients. FDA has extensive experience in evaluating the safety of such substances in food.

As to potential allergens, foods normally contain many thousands of different proteins. While the majority of proteins do not cause allergic reactions, virtually all known human allergens are proteins. Since genetic engineering can introduce a new protein into a food plant, it is possible that this technique could introduce a previously unknown allergen into the food supply or could introduce a known allergen into a "new" food. FDA's guidelines help developers to identify this issue and address any concern prior to marketing.

A second possible problem is the introduction of toxins into the food crop. It is possible that a new protein, as introduced into a crop as a result of the genetic modification, could cause toxicity. A third possible issue is the introduction of anti-nutrients, such as molecules like phytic acid that binds essential dietary minerals such as phosphorus.

Finally, use of genetic engineering techniques could result in unintended alterations in the amounts of substances normally found in a food -- for example, a reduction of Vitamin C or an increase in the concentration of a naturally occurring toxicant in the plant food.

It is important to note that the kinds of food safety testing typically conducted by developers of a bioengineered food crop to ensure that their foods meet all applicable requirements of the FD&C Act address these potential concerns. In the event that something unexpected does occur, this testing provides a way to detect such changes at the developmental stage and defer marketing until any concern is resolved.

LEGAL AND REGULATORY BACKGROUND

The overall federal regulatory structure for biotechnology products, known as the Coordinated Framework, was adopted by federal agencies in 1986 (51 FR 23302, June 26, 1986). Under the Coordinated Framework, FDA regulates bioengineered plant food in conjunction with the United States Department of Agriculture (USDA) and the Environmental Protection Agency (EPA). FDA has authority under the FD&C Act to ensure the safety of all domestic and imported foods for man or other animals in the United States market. The exceptions to this are meat, poultry and certain egg products, which are regulated by USDA. The safety of animal drug residues in meat and poultry, however, is regulated by FDA's CVM. Pesticides, including those bioengineered into a food crop, are regulated primarily by EPA, which reviews safety and sets tolerances (or establishes exemption from tolerance) for pesticides. FDA enforces the pesticide tolerances set by EPA. USDA's Animal & Plant Health Inspection Service (APHIS) oversees the agricultural and environmental safety of planting and field testing of bioengineered plants.

Bioengineered foods and food ingredients must adhere to the same standards of safety under the FD&C Act that apply to their conventionally-bred counterparts. This means that these products must be as safe as the traditional foods in the market. FDA has broad authority to initiate regulatory action if a product fails to meet the requirements of the FD&C Act.

FDA relies primarily on two sections of the FD&C Act to ensure the safety of foods and food ingredients that are produced using biotechnology:

(1) The adulteration provisions of section 402(a)(1). Under this postmarket authority, FDA has the power to remove a food from the market (or sanction those marketing the food) if the food poses a risk to public health. It is important to note that the FD&C Act places a legal duty on developers to ensure that the foods they market to consumers are safe and comply with all legal requirements.

(2) The food additive provisions in section 409. Under this section, a substance that is intentionally added to food is a food additive, unless the substance is generally recognized as safe (GRAS) or is otherwise exempt (e.g., a pesticide, the safety of which is overseen by EPA). Unapproved food additives are subject to the adulteration provisions in 402 (a)(2)(c) of the FD&C Act.

The FD&C Act requires premarket approval of any food additive, regardless of the technique used to add it to food. Thus, substances introduced into food are either (1) new food additives that require premarket approval by FDA or (2) GRAS, and are therefore exempt from the requirement for premarket review. Generally, foods such as fruits, vegetables, and grains are not subject to premarket approval because they have been safely consumed over many years. Other than the food additive system, there are no premarket approval requirements for foods generally.

In 1992, recognizing that bioengineered products were on the horizon, FDA published a policy explaining how existing legal requirements would apply to products developed using the tools of biotechnology (57 FR 22984; May 29,1992; "Statement of Policy: Foods Derived from New Plant Varieties"). The 1992 policy was designed to answer questions about these products and to assist developers prior to marketing to meet their legal duty to provide safe and wholesome foods to consumers. The basic principle of the 1992 policy is that the traits and characteristics of the foods should be the focus of safety assessment for all new varieties of food crops, no matter which techniques are used to develop them.

Under FDA policy, a substance that would be a food additive if it were added during traditional food manufacturing is also treated as a food additive if it is introduced into food through bioengineering of a food crop. Our authority under section 409 permits us to require premarket approval of any food additive and, thus, to require premarket approval of any substance intentionally introduced via bioengineering that is not generally recognized as safe.

Examples of substances intentionally introduced into food that would be reviewed as food additives include those that have unusual chemical functions, have unknown toxicity, or would be new major dietary components of the food. For example, a novel sweetener bioengineered into food would likely require premarket approval. In our experience with bioengineered food to date, however, we have reviewed only one substance under the food additive provisions, an enzyme produced by an antibiotic

resistance gene, and we granted approval as a food additive. In general, substances intentionally added to or modified in food via biotechnology to date have been proteins and fats that are, with respect to safety, similar to other proteins and fats that are commonly and safely consumed in the diet and, thus, are presumptively GRAS. Therefore, they have not needed to go through the food additive approval process.

In 1994, following the 1992 policy, FDA conducted a comprehensive scientific review for the first bioengineered product planned for introduction into the market. FDA reviewed Calgene's data on the Flavr SavrTM tomato and the use of the kanamycin resistance marker gene. Calgene submitted food additive petitions for the enzyme product of the marker gene for use in food and feed. We subsequently approved the petitions. FDA also held a public meeting of our Food Advisory Committee to examine applicability of the 1992 policy to products such as the Flavr SavrTM tomato. The Advisory Committee members agreed with FDA that the scientific approach presented in the 1992 policy was sound and that questions regarding the Flavr SavrTM had been addressed. The Advisory Committee members also suggested that we provide an expedited decision process for the marketing of bioengineered foods that do not raise substantive scientific issues.

In response, FDA established a consultative process to help companies comply with the FD&C Act's requirements for bioengineered foods that they intend to market. The results of our consultation are public information and are available on our website. Since the consultation process was created, companies have used the consultative process more than 50 times as they sought to introduce genetically altered plants representing more than ten different crops into the U.S. market. We are not aware of any bioengineered plant food that is subject to FDA's jurisdiction and is on the market that has not been evaluated by FDA through the current consultation process.

Typically, the consultation begins early in the product development stage, before it is ready for market. Company scientists and other officials meet with FDA scientists to describe the product they are developing. In response, the Agency advises the company on what tests would be appropriate for the company to assess the safety of the new food. After the studies are completed, the data and information on the safety and nutritional assessment are provided to FDA for review. The Agency evaluates the information for all of the known hazards and also for potential unintended effects on plant composition and nutritional properties, since plants may undergo changes other than those intended by the breeders. For example, FDA scientists are looking to assure that the newly expressed compounds are safe for food consumption, there are no allergens new to the food, no increased levels of natural toxicants, and no reduction of important nutrients. They are also looking to see whether the food has been changed in any substantive way such that the food would need to be specially labeled to reveal the nature of the change to consumers.

Some examples of the information reviewed by FDA include: The name of the food and the crop from which it is derived;

- The uses of the food, including both human food and animal feed uses;
- The sources, identities, and functions of introduced genetic material and its stability in the plant;
- The purpose or intended technical effect of the modification and its expected effect on the composition or characteristic properties of the food or feed;
- The identity and function of any new products encoded by the introduced genetic material, including an estimate of its concentration;
- A comparison of the composition or characteristics of the bioengineered food to that of food derived from the parental variety or other commonly consumed varieties with special emphasis on important nutrients, anti-nutrients, and toxicants that occur naturally in the food;
- Information on whether the genetic modification altered the potential for the bioengineered food to induce an allergic response; and,
- Other information relevant to the safety and nutritional assessment of the bioengineered food.

If a plant developer used a gene from a source whose food is commonly allergenic, FDA would presume that the modified food may be allergenic. The developer, however, is allowed the opportunity to demonstrate that such food would not cause allergic reactions in persons allergic to food from the source.

If FDA scientists have questions about the safety data, the company may, for example, provide more detailed answers or conduct additional studies. Our experience has been that no bioengineered product has gone on the market until FDA's questions about the safety of the product have been answered.

On January 18, 2001, FDA published a proposed rule to require that developers of bioengineered plant varieties notify FDA of their intention to market such products. FDA proposed that specific information be submitted to help determine wheth-

er the foods pose potential safety, labeling, or adulteration issues. The comment period for the proposed rule has closed and the Agency is in the process of evaluating the more than 100,000 comments received. The proposal has raised policy and legal concerns and is not a pressing public health priority for FDA, given that there is a voluntary consultation process in place that is working well.

LABELING

Section 403 of the FD&C Act sets labeling requirements for all foods. All foods, whether derived using bioengineering or not, are subject to these labeling requirements.Under section 403(a)(1) of the FD&C Act, a food is misbranded if its labeling is false or misleading in any particular way. Section 201(n) of the FD&C Act provides additional guidance on how labeling may be misleading. It states that labeling is misleading if it fails to reveal all facts that are "material in light of such representations (made or suggested in the labeling) or material with respect to consequences which may result from the use of the article to which the labeling or advertising relates under the conditions of use prescribed in the labeling or advertising thereof or under such conditions of use as are customary or usual."

While the legislative history of section 201(n) contains little discussion of the word "material," there is precedent to guide the Agency in its decision regarding whether information on a food is in fact material within the meaning of 201(n). Historically, the Agency has generally limited the scope of the materiality concept to information about the attributes of the food itself. FDA has required special labeling on the basis of it being "material" information in cases where the absence of such information may: (1) pose special health or environmental risks (e.g., warning statement on certain protein diet products); (2) mislead the consumer in light of other statements made on the label (e.g., requirement for quantitative nutrient information when certain nutrient content claims are made about a product); or (3) in cases where a consumer may assume that a food, because of its similarity to another food, has nutritional, organoleptic (i.e., affects taste, color, odor, or feel), or functional characteristics of the food it resembles when in fact it does not (e.g., reduced fat margarine not suitable for frying).

FDA does not require labeling to indicate whether or not a food or food ingredient is a bioengineered product, just as it does not require labeling to indicate which conventional breeding technique was used in developing a food plant. Rather, any significant differences in the food itself have to be disclosed in labeling. If genetic modifications materially change the composition of a food product, these changes must be reflected in the food's labeling. This would include its nutritional content (for example, more oleic acid, or greater amino acid or lysine content) or requirements for storage, preparation, or cooking, which might impact the food's safety characteristics or nutritional qualities. For example, one soybean variety was modified to alter the levels of oleic acid in the beans. Because the oil from this soybean is significantly different when compared to conventional soybean oil, we advised the company to adopt a new name for that oil, a name that reflects the intended change. If a bioengineered food were to contain an allergen not previously found in that food, information about the presence of the allergen would be material as to the potential consequences of consumption of the food. If FDA determined that labeling would be sufficient to enable the food to be safely marketed, the Agency would require that the food be labeled to indicate the presence of the allergen.

FDA has received comments suggesting that foods developed through modern biotechnology should bear a label informing consumers that the food was produced using bioengineering. We have given careful consideration to these comments. However, we do not have data or other information to form a basis for concluding that the fact that a food (or its ingredients) was produced using bioengineering is material within the meaning of 201(n) and therefore, constitutes information that must be disclosed as part of a bioengineered product's labeling. Hence, we believe that we have neither a scientific nor a legal basis to require such labeling. We have developed, however, draft guidance for those who wish voluntarily to label either the presence or absence of bioengineered food in food products. Comments to the draft guidance, which was issued in January 2001, are under review.

OFFICE OF SCIENCE AND TECHNOLOGY POLICY (OSTP) INITIATIVE

In August 2002, the Executive Office of the President, OSTP published a Notice in the Federal Register (67 FR 50578) which proposed coordinated actions by FDA, EPA, and USDA aimed at strengthening controls over field trials to address the potential of material from field trials inadvertently getting into food or feed.

FDA's task is to publish draft guidance for comment on procedures to address the possible intermittent, low-level presence in food and feed of new non-pesticidal pro-

teins from biotechnology-derived crops under development for food or feed use but that have not gone through FDA's premarket consultation process. Under this guidance, FDA would encourage sponsors (domestic and foreign) to submit protein safety information once field testing reached a stage of development such that there could be concerns that new non-pesticidal proteins produced in the field-tested plants might be found in food or feed. FDA's focus would be on proteins new to such plants, because FDA believes that at the low levels expected from such material, any food or feed safety concerns would be limited to the potential that a new protein could cause an allergic reaction in some people or could be a toxin. FDA would still anticipate that developers would conduct a complete consultation with FDA prior to marketing food or feed from the plant, consistent with current practices. The draft FDA guidance on this matter is under development at CFSAN.

PHARMACEUTICAL CROPS

FDA has the authority and responsibility for regulating pharmaceuticals, whether they are manufactured in a traditional manufacturing plant or they are manufactured in crops in the field. For crops in the field, however, there are additional issues to be addressed, including issues involving the parts of the plant that do not contain the pharmaceutical and the residual crop left over after a pharmaceutical is extracted. The White House National Economic Council and OSTP are coordinating a working group, including FDA, USDA, and EPA, with the cooperation of agencies concerned with international affairs and international trade, to look at this issue. Specifically, the group is working to clarify authorities for regulating genetically engineered crops, whether they are potential food crops, pharmaceutical crops, or industrial chemical crops, and to make sure there are no gaps in protecting human health and the environment. We are evaluating ways to help keep pharmaceutical and industrial chemical material out of food when it isn't supposed to be there, that would be science- and risk-based, that would be enforceable, that would not pose too high a barrier to development of these products, and that would be complementary with the APHIS regulatory scheme.

In September 2002, FDA and USDA published Draft Guidance for Industry on the use of bioengineered plants or plant materials to produce biological products, including medical devices, new animal drugs, and veterinary biologics. This draft guidance outlines the important scientific questions and information that should be addressed to FDA by those who are using bioengineered plants to produce medical or veterinary products. The comment period closed on February 7, 2003, and the approximately 600 comments received are under review.

PRODIGENE

In October 2002, commercial soybeans were harvested in Nebraska that contained a small number of immature bioengineered volunteer corn plants. The biotechnology firm, ProdiGene, had engineered the corn to produce pharmaceutical material. The harvested soybeans were subsequently commingled with approximately 500,000 bushels of other harvested soybeans. FDA, USDA, and the State of Nebraska made sure that the entire lot of soybeans was secured in a warehouse. ProdiGene agreed to buy back the lot of soybeans for disposal under government supervision.

Although the amount of genetically engineered material commingled with such a large amount of soybeans was very small and FDA was confident that there was no health risk, the material should not have been present in the soybeans. FDA, USDA and the State of Nebraska have ensured that these soybeans will not enter the human or animal food supply.

In the wake of the Nebraska incident, ProdiGene signed a settlement agreement requiring them to apply more stringent controls to any bioengineered plant it grows to produce a pharmaceutical product. FDA and USDA will continue to work closely together to enforce current safeguards covering research in bioengineered food crops.

OTHER ACTIVITIES

FDA has made a commitment to ensuring that consumers have access to information about new bioengineered food products in a timely fashion and has made more information about these foods available on FDA's website.

To ensure that FDA has the best scientific advice on issues related to bioengineered foods, we have added experts in this field to our foods and veterinary medicine advisory committees and created a Food Biotechnology Subcommittee of the Food Advisory Committee.

In addition, NAS has formed a standing committee on Agricultural Biotechnology, Health and the Environment. FDA, USDA, and EPA are currently sponsoring a

study by this committee on assessing the potential for unintended effects of genetically engineered foods and how to assess their impact on human health.

FDA has actively participated in the work with the Codex Ad Hoc Intergovernmental Task Force on Foods Derived from Biotechnology. The work of this task force is especially important because it has developed principles and guidelines for the evaluation of the safety of bioengineered foods internationally. This year the Codex Alimentarius Commission is expected to adopt principles for risk analysis and guidelines for safety assessment that will, when adopted, become international standards for ensuring the safety of genetically engineered foods. FDA has provided international leadership in this committee to develop harmonized policies for assessing the safety of bioengineered foods. The Codex guidelines are consistent with the way FDA approaches the evaluation of the safety of bioengineered foods.

FDA is also actively participating as a member of the Organization for Economic Co-operation and Development's Task Force for the Safety of Novel Foods and Feeds. This task force is in the process of writing scientific/technical consensus documents aimed at compiling current information that is important in food and feed safety assessment. These consensus documents serve as references to Codex and regulatory bodies.

Mr. Chairman, FDA, in cooperation with EPA and USDA, will continue its oversight of new and emerging food biotechnology products and will be vigilant in ensuring the safety and integrity of the food supply. I thank you again for the opportunity to address these issues. I am happy to answer any questions you might have.